

Applicants: Leslie Lobel and Joyce Lustbader
Serial No.: 09/804,626
Filed: March 9, 2001
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REMARKS

Claims 1, 2, 4, 7, 16, 18, and 24-26 are pending. No claims have been added, canceled, or amended herein.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the April 6, 2004, Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 2, 4, 7, 16, 18, and 24-26 under 35 U.S.C. §103(a) as allegedly unpatentable over Hsueh in view of McCoy, of record.

In response to the Examiner's rejection, applicants respectfully traverse, and maintain that the Examiner has failed to establish a *prima facie* case of obviousness because the Examiner has failed to demonstrate a suggestion to combine the cited references.

The rejected claims provide, in relevant part, a nucleic acid which encodes a soluble polypeptide comprising an extracellular domain of a gonadotropin receptor and thioredoxin. The claims also provide the encoded polypeptide.

Hsueh teaches a fusion protein comprising the extracellular domain of, e.g., the LH receptor, wherein the extracellular domain of the receptor is linked to a *transmembrane anchor protein*.

McCoy teaches that heterologous genes encoding *small* peptides may be expressed in bacteria as fusion proteins comprising a "thioredoxin-like" protein, which fusion proteins are both soluble and stable relative to the peptides alone.

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To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is *some teaching, suggestion, or motivation to do so* found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. M.P.E.P. §2143.01.

There is no explicit teaching or suggestion to combine in either McCoy or Hsueh. An implicit showing requires *objective evidence* and the making of *specific factual findings* with respect to the motivation to combine. *Id.* The Examiner asserts in the December 5, 2003 Office Action at page 5 that a person of ordinary skill in the art would have been motivated to make the fusion protein of the claimed invention because of the advantages taught by McCoy, namely that such a protein would be stable, soluble, and highly expressed, and useful as a therapeutic without cleavage.

However, the Examiner has provided no objective evidence or specific factual findings with respect to the motivation to combine McCoy with Hsueh to arrive at the claimed gonadotropin receptor thioredoxin fusion protein. The mere fact that references *can* be combined or modified does *not* render the resultant combination obvious unless the prior art also

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suggests the desirability of the combination. M.P.E.P. §2143.01. The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Id.*

In the absence of a showing of a motivation to combine, applicants maintain that the Examiner's rejection is improper and respectfully request that it be withdrawn.

In order to clarify their position, applicants point out that the art failed to actually provide the combination of references proposed by the Examiner during the eight years following issuance of the McCoy patent. This failure highlights the nonobviousness of the claimed invention.

In view of the above remarks, applicants maintain that claims 1, 2, 4, 7, 16, 18, and 24-26 satisfy the requirements of 35 U.S.C. §103(a).

Summary

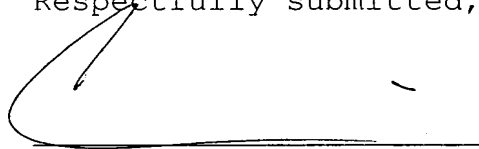
In view of the remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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